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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/546,143 04/10/00 MATZINGER

P 9473

000151
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HM22/0409

EXAMINER

TRUONG, T

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

04/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/546,143

Applicant(s)

MATZINGER ET AL.

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 February 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 10, 11, and 27 is/are allowed.
- 6) ☒ Claim(s) 12, 14, 15, 17, 19, 21, 23, and 25 is/are rejected.
- 7) ☒ Claim(s) 13, 16, 18, 20, 22, and 24 is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

FINAL ACTION

Applicant's amendment filed on 2-9-01 has been fully considered, but it has not placed the instant application in condition for allowance. All previous rejections and objections are maintained herein.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The amended claims 12, 14, 15, 17, 19, 21, 23, and 25 stand rejected under 35 U.S.C. 112, second paragraph because they recite R⁴ as an "amino protecting group" does not define the metes and bounds of the claim any more than the original phrase "protecting group". It is understood that R⁴ protects the ring nitrogen, and thus, it is an "amino protecting group". However, said phrase does not define the feature of R⁴. Applicant submits a list as a means to dispute the indefiniteness of the claim. Such a list, though, is inexhaustive and many of said groups do not have support in the instant disclosure. While breadth is not indefiniteness, **clarity and precision** are still required. Here, the phrase "amino protecting group" does not refer to a particular moiety, or functional group. See M.P.E.P. 2173.02. Also, **In re Wiggins** 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

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3. Said claims are also stay rejected under 35 U.S.C. 112, first paragraph for reasons stated in the last office action and for the one herein. The list of amino protecting group submitted by applicants does not have support in the instant disclosure. Furthermore, the regarding enablement for chemical cases, the M.P.E.P. explicitly states that:

...in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F. 2d 623, 624, 38 USPQ 189, 191 (CCPA 1938). In cases involving unpredictable factors, such as most **chemical reactions** and **physiological activity**, more may be required. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970)... See also *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 496, 20 USPQ 2d 1438, 1445 (Fed. Cir. 1991). This is because it is **not obvious** from the disclosure of one species, what other species will work. {M.P.E.P. 2164.03}

Also, as has been ruled by the court in *Genetech Inc. v. Novo Nordisk*, failure to disclose any specific starting material or any condition for preparation constitutes lack of enablement. Thus, relying on the knowledge of one skilled in the art cannot cure such deficiency in enablement (*Genetech Inc. v. Novo Nordisk*, 108 F.3d 1361, 42 USPQ 2d 1001 (Fed. Cir. 1997)).

In the instant case, only one amino protecting group is named in the specification. Thus, there is no correlation if other amino protecting groups will also work under the same reaction conditions.

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Claim Rejections - 35 USC § 102

By simply changing R⁴ to an “amino protecting group” does not overcome anticipation set forth in the previous office action.

4. Claim 23 remains rejected under 35 U.S.C. 102(a) as being anticipated by **Lampe et. al.** for reasons stated previously.

5. Claims 17, 23, and 25 stay anticipated by **Krogsgaard-Larsen et. al.** and **Adams et. al.** under 35 U.S.C. 102(b).

6. Claim 25 stands anticipated by **Barbier et. al.** under 35 U.S.C. 102(e).

Claim Rejections - 35 USC § 103

7. Claims 25 and 26 stay rejected under 35 U.S.C. 103(a) as being unpatentable over **Barbier et. al.** for reasons stated in the last office action. As mentioned in the 102 rejections above, by changing R⁴ to an “amino protecting group” does not overcome the teaching of **Barbier et. al.**

Claim Objections

8. Claims 13, 16, 18, 20, 22, and 24 remain objected.

Allowable Subject Matter

9. Claims 10, 11, and 27 are allowable for reasons stated in the previous office action.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

T. Truong

April 5, 2001



Mukund J. Shah
MUKUND J. SHAH
SUPERVISORY PATENT EXAMINER
GROUP 1200